(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 December 2004 (02.12.2004)

PCT

(10) International Publication Number
WO 2004/103214 A1

(51) International Patent Classification[7]: A61F 2/04

(21) International Application Number:
PCT/US2004/001601

(22) International Filing Date: 21 January 2004 (21.01.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PCT/US03/15731 20 May 2003 (20.05.2003) US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US PCT/US03/15731 (CIP)
Filed on 20 May 2003 (20.05.2003)

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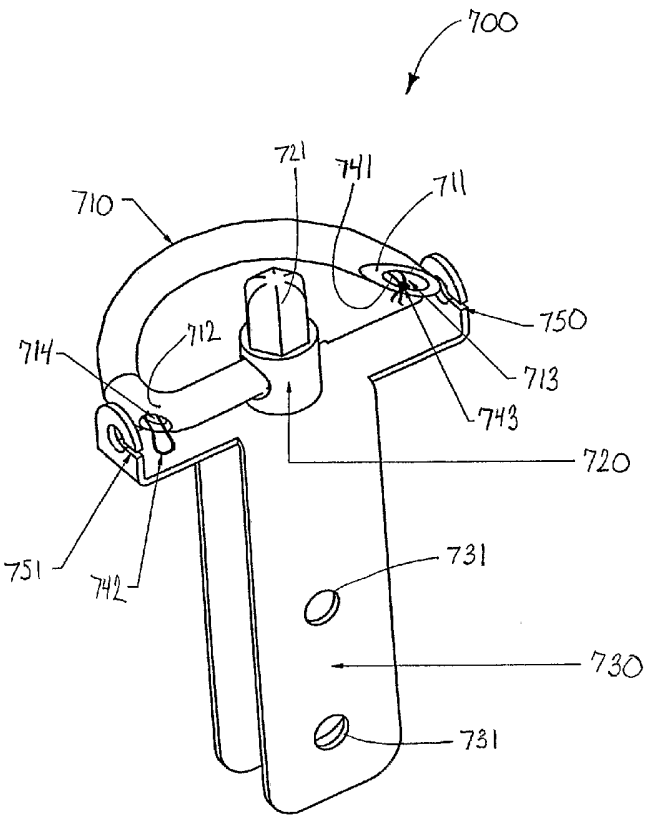
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),

[Continued on next page]

(54) Title: IMPROVED APPARATUS AND METHOD FOR SECURING TO AN INTERNAL WALL OF A BIOLOGICAL LUMEN



(57) Abstract: An improved apparatus and method for securing to an internal wall of a biological lumen. In one aspect the invention is an apparatus comprising: a curved needle having a lead end and a trailing end, the curved needle pivotable about an axis between an open position and a closed position and adapted to pierce and engage the internal wall of the lumen when pivoted from the open position to the closed position; a needle cavity extending through the curved needle; a loop of string having a rear portion and a forward portion having a snag; and the loop of string positioned within the needle cavity so that the snag protrudes from the needle cavity at or near the lead end of the curved needle. In another aspect, the invention is a method of securing the inventive apparatus to the internal wall using solely the loop of string.

WO 2004/103214 A1

Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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DEVICE FOR SECURING TO WALL OF INTERNAL LUMEN

Cross Reference to Related Application

[0001] This application is a continuation-in-part of, and claims priority, to PCT/US03/15731, filed May 20, 2003, which is hereby incorporated by reference in its entirety.

Field of the Invention

[0002] This invention relates generally to the field of internal medical devices, and specifically to methods and apparatus for securing medical devices to the internal walls of biological lumens.

Background Art

[0003] Medical devices are inserted into biological lumens for a variety of reasons. For example, in the treatment of gastroesophageal reflux disease (GERD), a medical prosthesis, such as that shown in United States Patent 5,861,036, Godin, is inserted into the esophagus. In order to prevent gastric juices from refluxing into the esophagus and causing esophageal mucosal injury ("esophagitis"), the medical prosthesis must remain properly positioned within the esophagus.

[0004] Getting medical devices, such as a prosthesis used to treat GERD, to remain properly positioned within a body lumen for an extended period of time has proven to be a significant challenge in the medical field. While ensuring that devices are properly sized has helped reduce the problem, it is still common for internal medical devices to shift and/or disengage from their proper position within the biological lumen despite proper sizing. Current methods for securing medical devices to the internal wall of the desired lumen include suturing, gluing, and using suction/aspiration. However, none of these techniques have proven to be satisfactory.

[0005] Glues, such as cyanacrylates, are commonly used to secure medical devices to the internal wall of the desired biological lumen by applying the glue to the exterior of the medical device and holding the device in contact with internal wall. Using glues presents a number of problems. First, glues dry very quickly and can result in the medical device prematurely bonding in an undesired orientation. Once adhered, glues are not easily reversible and further moving the medical device is difficult. Additionally, glues can cause problems when being handled with an endoscope. Often the endoscope or optics can end up being glued to the medical device itself or the optics of the endoscope can be opacified by the glue itself.

[0006] Suturing is another method of securing medical devices to the internal wall of a biological lumen. Suturing is unsatisfactory in that space can be very limited within the lumen, causing the suturing job to be very difficult. This can result in the doctor obtaining a less than optimal suture. Additionally, suturing is usually done by suctioning tissue and placing a needle and thread through the suctioned tissue. Thus, the sutures are usually not place very deep and fall out easily and fairly rapidly.

[0007] Another method that exists for securing medical devices within the lumen is the use of aspiration/suction to induce a proturbence of the mucosa into a cavity of the medical device. Such a method is disclosed in United States Patent 6,285,897, Kilcoyne, which is hereby incorporated by reference. Suction has proven to be unsatisfactory in that the medical device will slough off with the mucosa in a matter of days and can not be used to secure the medical device to the internal wall for an extended duration.

Disclosure of the Invention

[0008] It is therefor an object of the present invention to provide a method and apparatus for insertion into a biological lumen that more securely engages an internal wall of the biological lumen.

[0009] Another object is to provide a method and apparatus for insertion into a biological lumen that can remain secured to the internal wall of the biological lumen for an extended period of time.

[0010] Yet another object is to provide a method and apparatus for insertion into a biological lumen that remains properly positioned.

[0011] A further object of the present invention is to provide a method and apparatus for insertion into a biological lumen that can be easily secured to the internal wall of the biological lumen.

[0012] A still further object is to provide a method and apparatus for insertion into a biological lumen that can be easily removed from the internal wall of the biological lumen after it is secured thereto.

[0013] Still another object is to provide a method and apparatus for insertion into a biological lumen that does not interfere with an endoscope or other optics while being secured to the internal wall.

[0014] It is a further object to provide a method and apparatus for insertion into a biological lumen that provides minimal discomfort to the patient and quick healing.

[0015] These objects and others are met by the present invention, which in one aspect is an apparatus for securing to an internal wall of a biological lumen comprising: a curved needle having a lead end and a trailing end, the curved needle pivotable about an axis between an open position and a closed position and adapted to pierce and engage the internal wall of the lumen when pivoted from the open position to the closed position; a needle cavity extending through the curved needle; a loop of string having a rear portion and a forward portion having a snag; and the loop of string positioned within the needle cavity so that the snag protrudes from the needle cavity at or near the lead end of the curved needle. Preferably, the loop of string is positioned in the needle cavity so that the rear portion of the loop of string protrudes from the needle cavity at or near the trailing end of the curved needle.

[0016] The term biological lumen as used herein is meant to include body cavities and/or orifices. The biological lumen can be, for example, the stomach, colon, rectum, bladder, uterus, vagina, biliary ducts (including the common bile duct), or blood vessels. When the biological lumen is the esophagus, the apparatus will be an anti-reflux device, such as that disclosed in United States Patent 5,861,036 or United States Application Publication 2003/0009236, both

of which are incorporated by reference herein. The term "esophagus" in this discussion includes the lower esophageal sphincter (LES).

[0017] The depth of the suture formed by the present invention depends on the radius of the curved needle (i.e., the curvature of the needle). The curvature can be adapted so as to obtain a depth of the suture that one chooses, resulting in more solid sutures that last longer.

[0018] The snag in the forward portion of the loop of string can be a simple knot tied into the string . Preferably, the string is surgical thread, size 2.0. The snag is preferably sized so that it does not fit into the needle cavity. Sizing the snag so that it can not fit into the needle cavity prevents the loop of string from being pushed into the needle cavity during piercing of the internal wall by the curved needle.

[0019] Preferably, the apparatus has a body to which the curved needle is pivotally mounted. The body can be a clip body that is then secured to a medical device or the body can be portion of the medical device itself. In this embodiment, a first post is preferably supplied on the body for receiving and securing the forward portion of the loop of string. A second post is also preferably provided on the body for receiving and securing the rear portion of the loop of string. The first and second posts can be substantially C-shaped. This allows the loop of string to be adequately secured to and removed from the posts easily. The suture formed by the loop of string can be easily cut at the C-shaped posts with existing endoscopic suture cutting devices.

[0020] The curved needle is preferably designed so that it is removable from the body. This can be accomplished by pivotally mounting the curved needle to the body with a tight fit or pop-fit assembly, such as a stub and cavity. In order to facilitate rotation of the curved needle about its axis, the curved needle preferably extends from a hub that is adapted to be engaged by a rotational tool. For example, the top of the hub an be shaped as a bolt head.

[0021] In another aspect, the invention is a method of securing an apparatus to an internal wall of a biological lumen. According to the inventive method, the apparatus is first provided comprising a curved needle pivotally mounted to a body, the curved needle having a lead end and a trailing end, the curved needle

pivotable about an axis between an open position and a closed position and adapted to pierce and engage the internal wall of the lumen when pivoted from the open position to the closed position, a needle cavity extending through the curved needle from the lead end to the trailing end, a loop of string having a rear portion and a forward portion having a snag, the loop of string positioned within the needle cavity so that the snag protrudes from the needle cavity at or near the lead end of the curved needle and the rear portion of the loop of string protrudes from the needle cavity at or near the trailing end of the curved needle. The apparatus is inserted into the desired biological lumen with the curved needle in the open position. Once in the desired position within the lumen, the curved needle is pivoted about the axis to the closed position thereby causing the curved needle to pierce and engage the internal wall. As such, the leading end of the curved needle re-enters the internal space of the lumen and the forward portion of the loop of string is secured to a first post or the body. The curved needle is then rotated back to the open position, causing the loop of string to slide out of the needle cavity. Once back in the open position, the rear portion of the loop of string is secured to a second post. As such, the apparatus will be supported solely to the internal wall by the loop of string which extend through the path initially formed by the curved needle. The curved needle can then be removed from the body and taken out of the lumen to prevent obstruction.

[0022] Preferably, the lumen is an esophagus and the apparatus is an implantable anti-reflux device.

Brief Description of the Drawings

[0023] Figure 1 is a side view of a balloon catheter positioned in an esophagus.

[0024] Figure 2 is a top perspective view of a clip assembly having a pivotable curved needle according to one embodiment of the present invention.

[0025] Figure 3 is an exploded view of the clip assembly embodiment of FIG. 2.

[0026] Figure 4 is a perspective view an endoscopic rotational tool about to engage the clip assembly of FIG. 2 connected to a section of a wall of an anti-reflux prosthesis.

[0027] Figure 5 is a side, partially cut-away view of an anti-reflux prosthesis, partially in section, according to an embodiment of the present invention inserted within an esophagus, illustrated in cross-section

[0028] Figure 6 is a perspective view of an embodiment of a clip assembly according to the present invention with a female socket.

[0029] Figure 7 is a perspective view a clip assembly incorporating a hollow curved needle and a loop of string according to another aspect of the present invention.

[0030] Figure 8 is a perspective view of a section of a wall of an anti-reflux prosthesis having the clip assembly of FIG. 7 connected thereto and positioned within an esophagus, the curved needle being in the open position.

[0031] Figure 9 is a perspective view of the anti-reflux prosthesis of FIG. 8 wherein the curved needle is in the closed position and a forward portion of the loop of string is being secured to a C-shaped post.

[0032] Figure 10 is a perspective view of the anti-reflux prosthesis of FIG. 8 wherein the curved needle is removed from the clip body and the loop of string is secured to both C-shaped posts.

[0033] Figure 11 is a perspective view of the loop of string removed from the needle cavity of the clip assembly of FIG. 7 according to an embodiment of the invention.

Modes for Carrying Out the Invention

[0034] Referring first to FIG. 1, a balloon catheter is inserted into esophagus **30** to determine the size of esophagus **30** and thereby the proper size of the ring of the anti-reflux prosthesis **400** (FIG. 5) for insertion. Balloon catheter **10** comprises balloon **11**, syringe **12** and pressure monitor **13** (illustrated as a generic box). In order to determine the diameter of the internal wall **31** of esophagus **30**, balloon **11** is inserted into esophagus **30** until it reaches the location to be sized. Once in position, balloon **11** is inflated by depressing plunger **14** of syringe **12** which is filled air, oxygen, or some other gas. Balloon **11** is inflated by syringe **12** until balloon **11** contacts internal wall **31** of esophagus **30**. Upon contacting internal wall **31** of esophagus **30**, an increase in pressure is detected by pressure monitor **13**. The volume of air

supplied to balloon **11** by syringe **12** is recorded and correlated to a specific balloon diameter. This diameter is used to choose an appropriately sized anti-reflux prosthesis for insertion into esophagus **30**. Balloon **11** is deflated and removed from esophagus **30**.

[0035] Referring now to FIGS. 2 and 3, an embodiment of a clip assembly **200** comprises clip body **210**, curved needle **220**, stopper **230**, hub **240**, and sleeve **250**. Clip body **210** is a rigid structure and comprises top plate **211**, front plate **212**, and back plate **213**. Front plate **212** and back plate **213** have teeth **215**. Teeth **215** are adapted to secured clip assembly **200** to wall **610** (FIG. 4) of anti-reflux device **400** (FIG. 5) by either biting into wall **610** or fitting into corresponding indentations.

[0036] Referring to Fig. 3, curved needle **220** is substantially semi-circular shaped and protrudes from side wall **243** of hub **240**. Hub **240** also comprises cylindrical stub **241** protruding from its bottom. Sleeve **250** forms sleeve cavity **251**. Sleeve **250** is positioned between front plate **212** and back plate **213** so that sleeve cavity **251** is substantially aligned with hole **214** of top plate **211**. When assembled, cylindrical stub **241** extends through hole **214** of top plate **211** and into sleeve cavity **251** of sleeve **250**. Cylindrical stub **242** is sized and shaped to form a tight fight with sleeve cavity **251** while still allowing rotation/pivoting therewith. As such, curved needle **220** is pivotally connected to clip body **210**, allowing rotation/pivoting about axis **A-B**.

[0037] Referring now to FIG. 4, hub **240** also comprises bolt head **242**. As illustrated in FIG. 4, bolt head **242** is adapted to be engaged by rotational tool **350** so that curved needle **220** can be rotated about axis **A-B** (FIG 3) in both a clockwise and counterclockwise direction. Curved needle **220** is illustrated in a closed position. If curved needle **220** is rotated 180 degrees counter-clockwise, it would be an open position. When in the open position (NOT illustrated), no portion of curved needle **220** extends beyond outer surface **611** of wall **610**. When curved needle **220** is in the open position and bolt head **242** is rotated in a clockwise direction, curved needle **220** will rotate in a clockwise direction until it contacts stopper **230**. Once curved needle contacts

stopper **230**, stopper **230** prevents curved needle from rotating any further in the clockwise direction.

[0038] In another embodiment, stopper **230** can be adapted so as to not interfere with the rotation of curved needle of **220** about axis **A-B**. In this embodiment, sleeve **250** can be adapted to act as a stopper if desired. Additionally, sleeve **250** can be sized so that the tight fit between cylindrical stub **241** and sleeve cavity **251** does not allow free rotation of curved needle about axis **A-B** without force being exerted by rotational tool **350**.

[0039] Clip assembly **200** is secured to wall **610** of anti-reflux prosthesis **400** through the use of teeth **215**, as is illustrated in FIG. 4. Anti-reflux prosthesis **400** is inserted into an esophagus **30** with all of the curved needles **220** in an open position. In FIG 5 the curved needle **220** illustrated on the left is shown in the open position. When in the open position, curved needle **220** does not engage internal wall **31** and does not interfere with the insertion/placement of anti-reflux prosthesis **400** in esophagus **30**.

[0040] In operation, the anti-reflux prosthesis **400** is first positioned in the desired location within esophagus **30**, and then each curved needle **220** is pivoted about axis **A-B** from the open position to a closed position. The curved needle **220** illustrated on the right is shown in the closed position. As curved needle **220** is pivoted from the open position to the closed position, curved needle **220** pierces and engages internal wall **31**, securing anti-reflux prosthesis in place. Once secured to internal wall **31**, anti-reflux prosthesis **400** can be removed by pivoting all of the curved needles **220** back into the open position. All pivoting of curved needle **220** within esophagus **30** can be accomplished with rotational tool **350** (FIG. 4) through the use of an endoscope.

[0041] In another method of using the present invention, anti-reflux prosthesis **400** is inserted and positioned within esophagus **30** with each curved needle **220** in the closed position. This closed orientation ensures that curved needle **220** does not prematurely pierce or cut internal wall **31** during insertion and positioning. Once inserted, each curved needle **220** will be rotated 360 degrees in the appropriate direction instead of 180 degrees.

[0042] Referring now to FIG. 6, hub **240** can be modified to be compatible with any type of rotational device. As illustrated, hub **240** can have a female socket **245** instead of a bolt head for facilitating pivoting of curved needle **220**. The female socket **245** can receive a male-ended rotational device rather than a female-ended device **350**.

[0043] Figures 7-11 illustrate a clip assembly according to another aspect of the present invention. The clip assembly of FIGS.7-11 uses an alternative method and design to secure a device to the internal wall of the lumen.

[0044] FIG. 7 illustrates clip assembly **700** in a closed position. Clip assembly **700** comprises hollow needle **710** extending from hub **720**. Hollow needle **710** is pivotally mounted to clip body **730** in a manner similar to that described above. Clip body **730** comprises connection holes **731** for facilitating connection to the medical device to be secured within a lumen.

[0045] Hollow needle **710** comprises leading end **711** and trailing end **712**. A needle cavity extends through hollow needle **710** from opening **713** at leading end **711** to opening **714** at trailing end **712**. Hub **720** comprises bolt-head **721** for engagement by a rotational tool so that hollow curved needle **710** can be pivoted between an open position (FIG. 8) and the closed position.

[0046] Referring now to FIG. 11, a single loop of string **740** is positioned within and extends through the needle cavity of hollow needle **710**. Loop of string **740** comprises a forward portion **741** and rear portion **742**. Forward portion **741** comprises a knot **743** tied therein. Loop of string **740** is preferably made out of size 2.0 surgical threading. However, the present invention is not limited to the string being of any specific size or type of material, so long as the material is qualified for internal use. As used herein, a "loop of string" encompasses string formed into a single loop or string having a loop formed at each of it ends.

[0047] Referring back to FIG. 7, loop of string **740** is positioned within the needle cavity so that its forward portion **741** protrudes from opening **713** while its rear portion **742** protrudes from opening **714**. Knot **743** is preferably sized to not fit within opening **713**. As such, knot **743** will act as a snag, preventing forward portion **741** from getting pushed into and trapped in the needle cavity.

As used herein, a "snag" encompasses any device or item that can be placed onto or incorporated into loop of string **740** that will help prevent the forward portion **741** from getting jammed into the needle cavity.

[0048] Posts **750** and **751** are located on clip body **730**. Posts **750** and **751** are substantially C-shaped. As such, forward and rear portions **741** and **742** of loop of string **740** can be easily placed over the posts and adequately secured thereto. However, the posts can be any shape such as linear, curved, or a combination of the two. Alternatively, the posts do not have to located on a clip body but can be built into the body of the medical device itself.

[0049] FIG. 8 illustrates clip assembly **700** secured to wall **810** of an anti-reflux prosthesis. Clip assembly **700** is in the open position. In using clip assembly **700** to secure an anti-reflux prosthesis to internal wall **910** of esophagus **900**, clip assembly **700** is first attached to wall **810** of the anti-reflux prosthesis using connection holes **731**. The anti-reflux prosthesis is then inserted into esophagus **900** until it is at the desired position. Curved needle **710** remains in the open position during insertion.

[0050] Once the anti-reflux prosthesis is in the desired position, curved needle **710** is rotated clockwise with a rotational tool that engages bolt head **721**. As curved needle **710** is rotated clockwise, lead end **711** (FIG. 7) of curved needle **710** pierces and travels through wall **910**. As curved needle **710** continues to be rotated clockwise toward the closed position, lead end **711** exits wall **910** near post **750**. Knot **743** on loop of string **740** prohibits the string from getting jammed into the needle cavity during rotation.

[0051] Referring now to FIG. 9, curved needle **710** is illustrated in the closed position after rotation from the open position. Once in the closed position, forward portion **741** of string of loop **740** is near post **750** while rear portion **742** is near post **751**. Forward portion **741** is then grasped by endoscopic forceps and placed over post **750**. Once forward portion **741** is secured to substantially post **750**, curved needle **710** is rotated counter-clockwise back to the open position using the rotational tool. As curved needle **710** is rotated back to the open position, the loop of string **740** pulls out of the needle cavity because forward portion **741** is secured to post **750**. Once curved needle **710**

is back into the open position and loop of string **740** is pulled entirely out of the needle cavity, rear portion of loop of string **740** is grasped by endoscopic forceps and placed over post **751**.

[0052] FIG. 10 illustrates loop of string **40** secured to both posts **750** and **751.** As such, the anti-reflux prosthesis is secured to wall **910** solely by loop of string **740**. Once loop of string **740** is properly secured to posts **750** and **751**, curved needle **710** is removed from clip body **730** with an endoscopic snare and removed from the esophagus. Curved needle **710** is pivotally mounted to clip body **730** in a removable fashion through the use of stub **722** which pop-fits into hole **770**.

[0053] While the invention has been described and illustrated in sufficient detail that those skilled in this art can readily make and use it, various alternatives, modifications, and improvements should become readily apparent without departing from the spirit and scope of the invention. Specifically, the use of a clip body is not necessary and the body of the medical device itself can be adapted to pivotally mount the curved needle.

Claims

What is claimed is:

1. An apparatus for securing to an internal wall of a biological lumen comprising:

a curved needle having a lead end and a trailing end, the curved needle pivotable about an axis between an open position and a closed position and adapted to pierce and engage the internal wall of the lumen when pivoted from the open position to the closed position;

a needle cavity extending through the curved needle;

a loop of string having a rear portion and a forward portion having a snag; and

the loop of string positioned within the needle cavity so that the snag protrudes from the needle cavity at or near the lead end of the curved needle.

2. The apparatus of claim 1 wherein the snag is sized to not fit into the needle cavity.

3. The apparatus of claim 1 further comprising a body, the curved needle being pivotally mounted to the body.

4. The apparatus of claim 3 wherein the body is a clip body adapted to be secured to a medical device.

5. The apparatus of claim 3 wherein the body is a body of a medical device.

6. The apparatus of claim 3 further comprising a first post on the body for receiving and securing the forward portion of the loop of string.

7. The apparatus of claim 6 further comprising a second post on the body for receiving and securing the rear portion of the loop of string.

8 The apparatus of claim 7 wherein the first and second posts are substantially C-shaped.

9. The apparatus of claim 3 wherein the curved needle is removable from the body.

10. The apparatus of claim 9 wherein the curved needle is pivotally mounted to the body by a tight-fit or pop-fit sembly.

11. The apparatus of claim 1 wherein the curved needle extends from a hub adapted to be engaged by a rotational tool.

12. The apparatus of claim 1 wherein the snag is a knot.

13. The apparatus of claim 1 wherein the loop of string is positioned in the needle cavity so that the rear portion of the loop of string protrudes from the needle cavity at or near the trailing edge of the curved needle.

14. An apparatus for securing to an internal wall of a biological lumen comprising:

a curved needle having a lead end and a trailing end;

the curved needle pivotally mounted to a body for rotation about an axis between an open position and a closed position, the curved needle adapted to pierce and engage the internal wall of the lumen when pivoted from the open position to the closed position;

a needle cavity extending through the curved needle;

a loop of string having a rear portion and a forward portion having a knot that is sized to not fit into the needle cavity;

the loop of string positioned within the needle cavity so that the knot protrudes from the needle cavity at or near the lead end of the curved needle and

the rear portion of the loop of string protrudes from the needle cavity at or near the trailing end of the curved needle;

a first post on the body for receiving and securing the forward portion of the loop of string;

a second post on the body for receiving and securing the rear portion of the loop of string; and

wherein the first and second posts are substantially C-shaped.

15 A method of securing an apparatus to an internal wall of a biological lumen comprising:

providing an apparatus comprising a curved needle pivotally mounted to a body, the curved needle having a lead end and a trailing end, the curved needle pivotable about an axis between an open position and a closed position, a needle cavity extending through the curved needle from the lead end to the trailing end, a loop of string having a rear portion and a forward portion having a snag, the loop of string positioned within the needle cavity so that the snag protrudes from the needle cavity at or near the lead end of the curved needle and the rear portion of the loop of string protrudes from the needle cavity at or near the trailing end of the curved needle;

inserting the apparatus into the biological lumen with the curved needle in the open position;

pivoting the curved needle about the axis to the closed position thereby causing the curved needle to pierce and engage the internal wall;

securing the forward portion of the loop of string to a first post on the body;

pivoting the curved needle back to the open position; and

securing the rear portion of the loop of string to a second post on the body.

16. The method of claim 14 wherein the first and second posts are substantially C-shaped.

17. The method of claim 14 further comprising the step of removing the curved needle from the body and out of the lumen.

18. The method of claim 14 wherein the snag is a knot.

19. The method of claim 14 wherein the lumen is an esophagus and the apparatus is an implantable anti-reflux device.

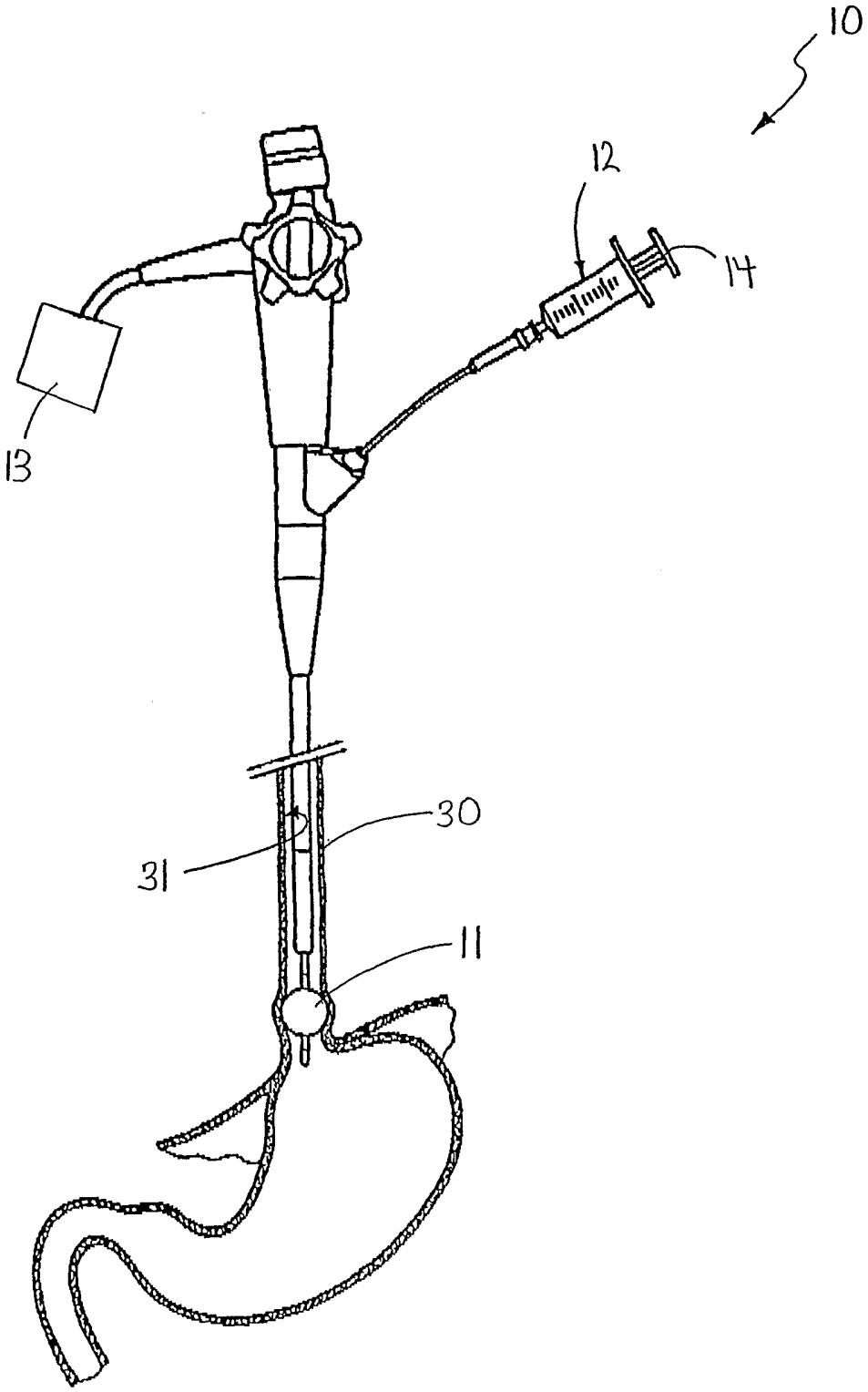


Fig. 1

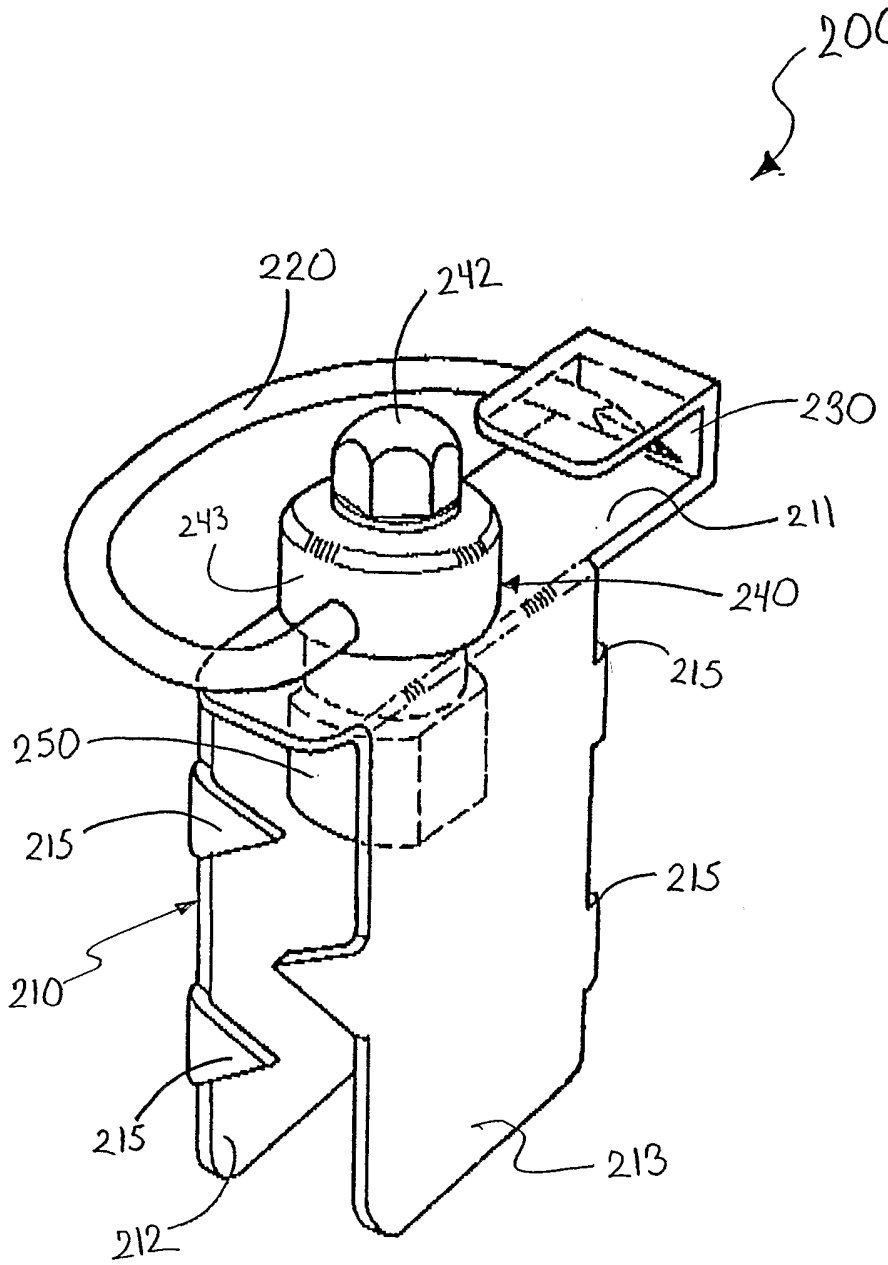
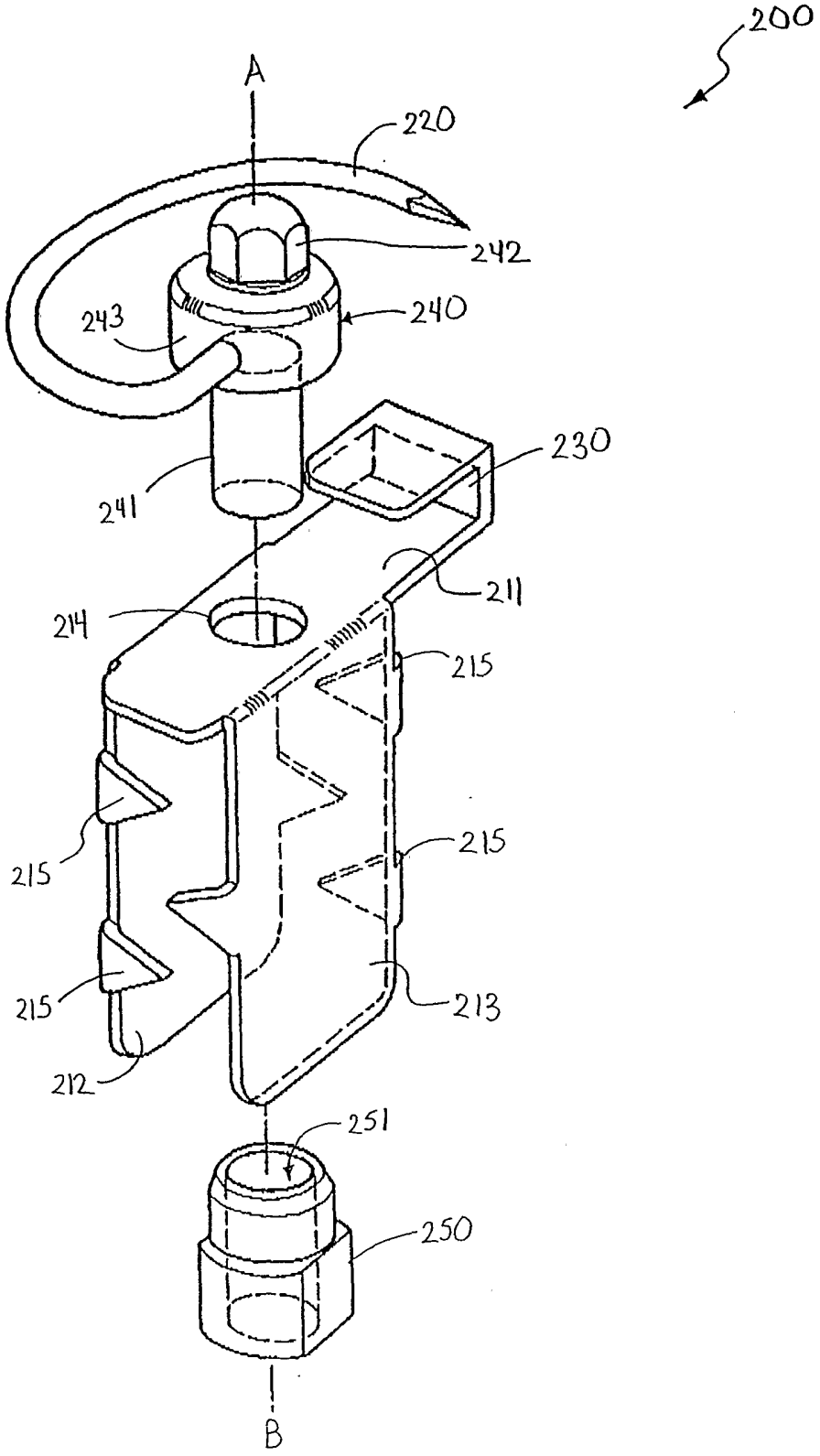


Fig. 2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B

Fig. 3

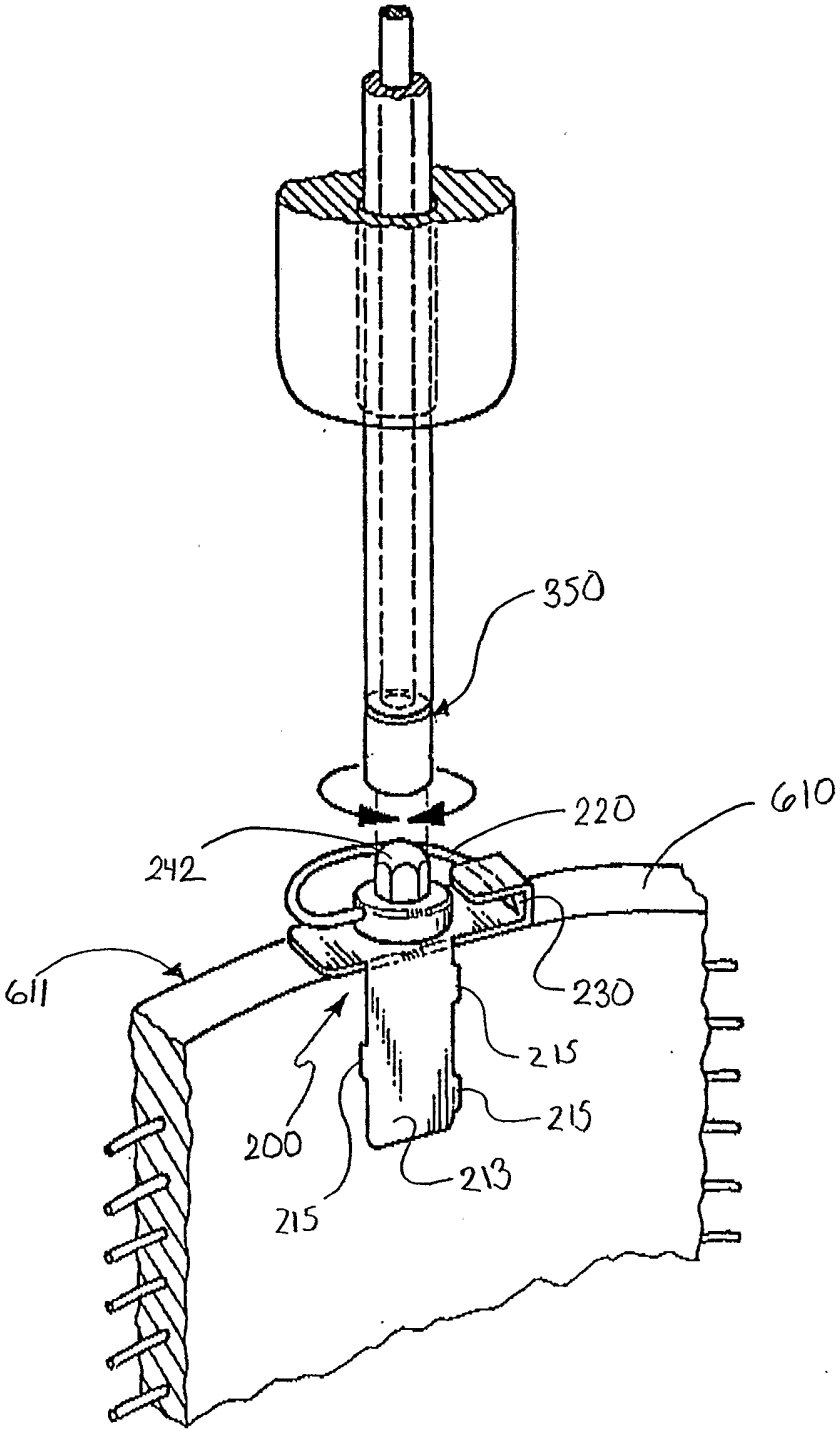

Fig. 4

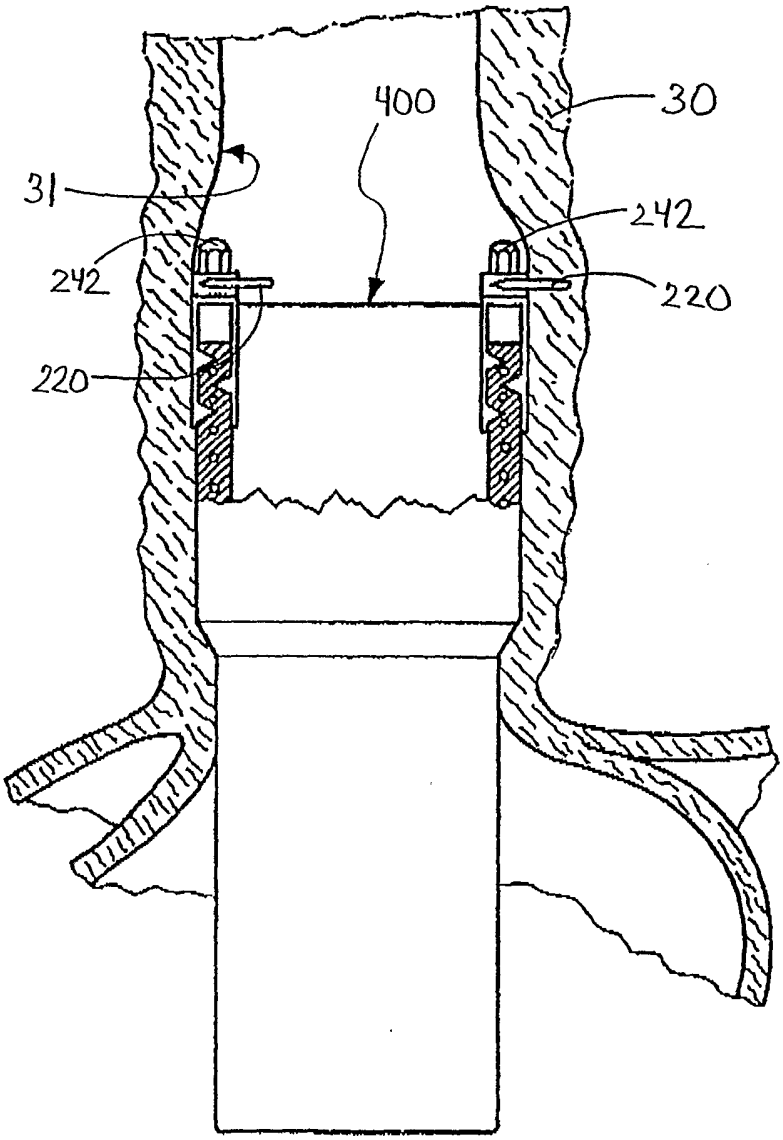

Fig. 5

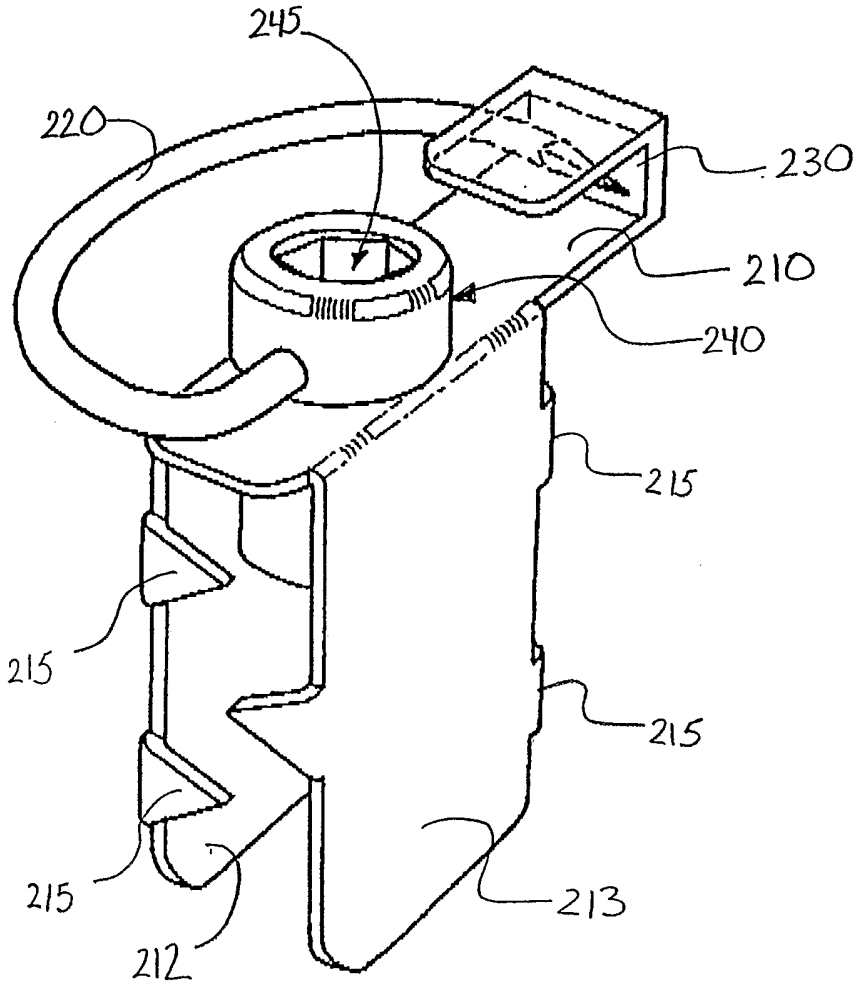

Fig. 6

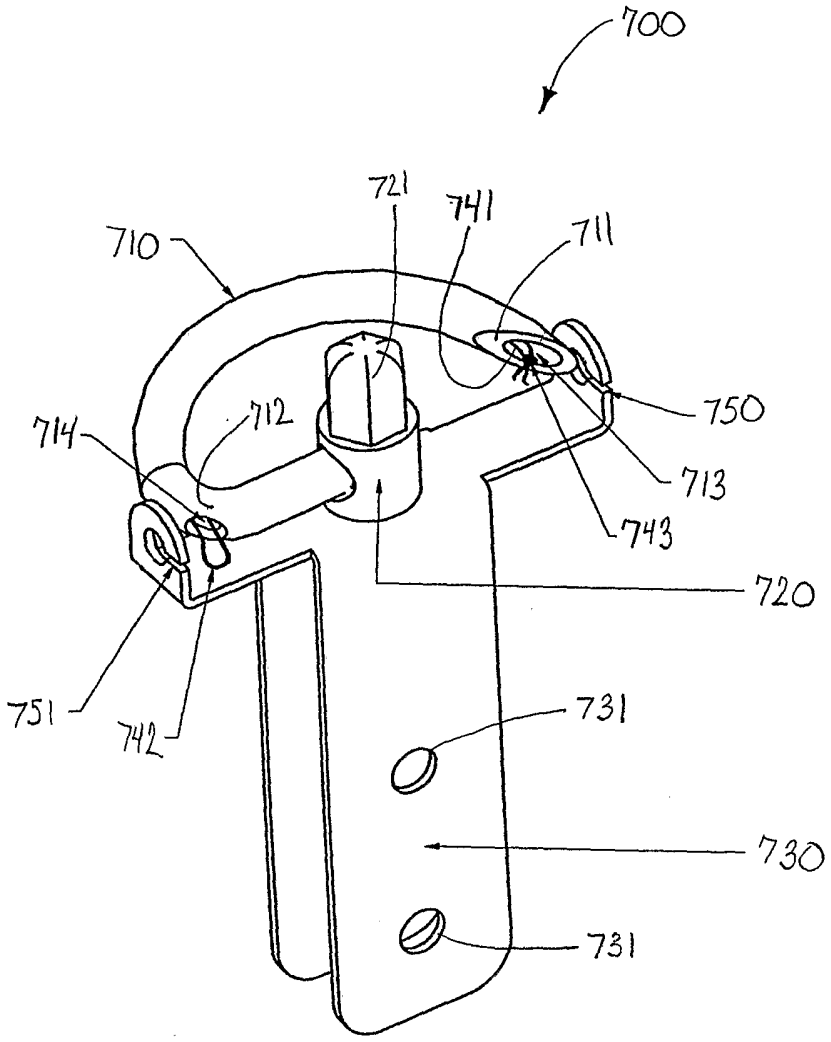

Fig. 7

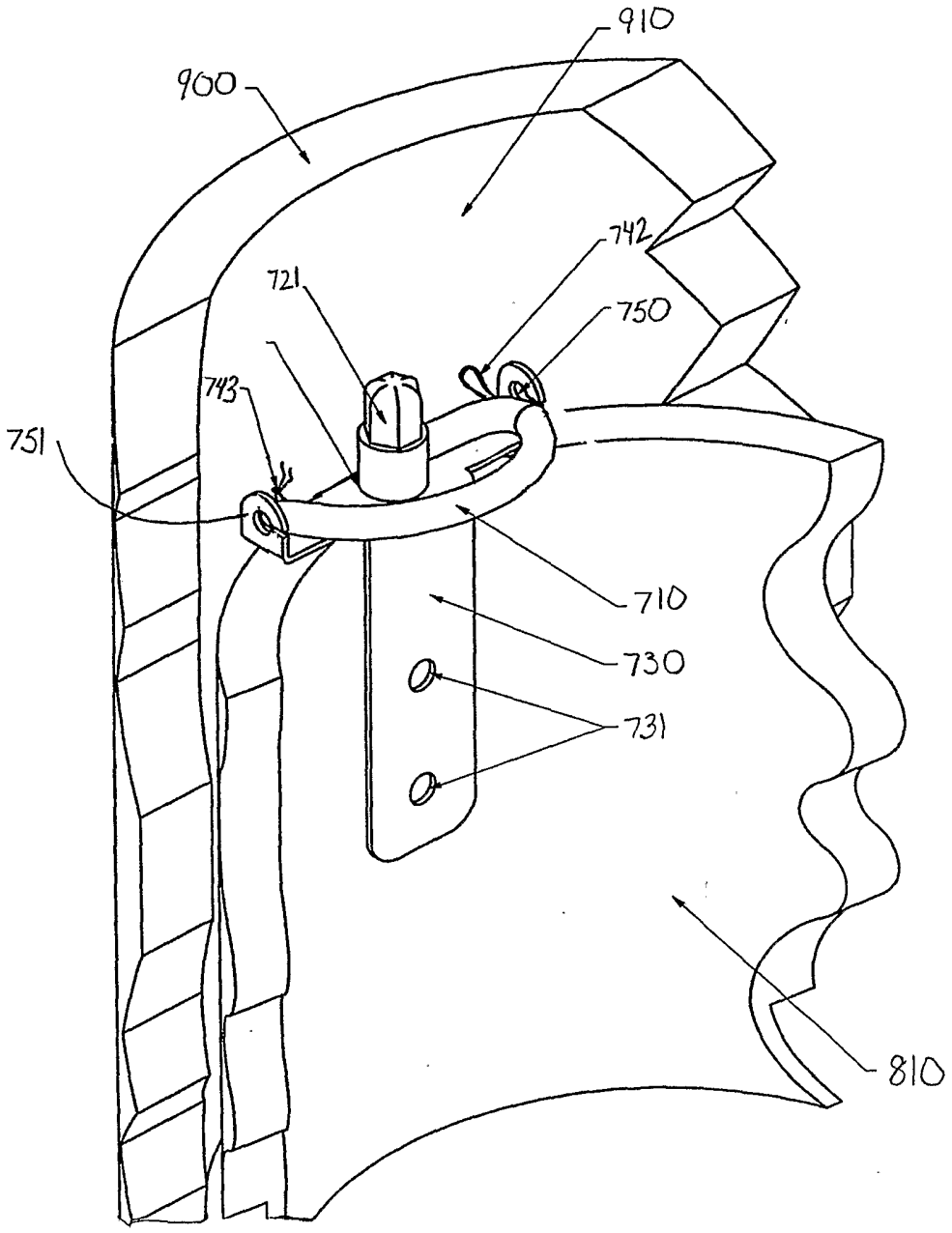

Fig. 8

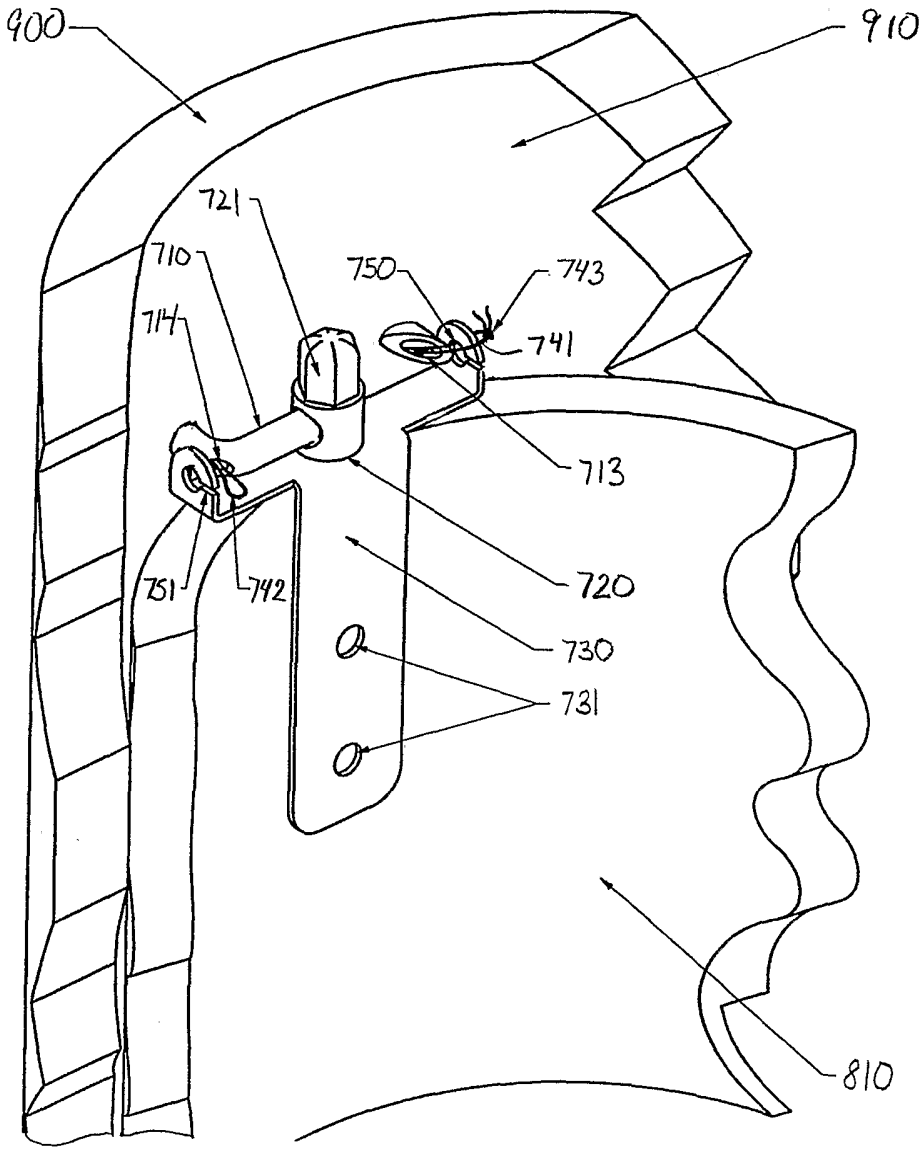

Fig. 9

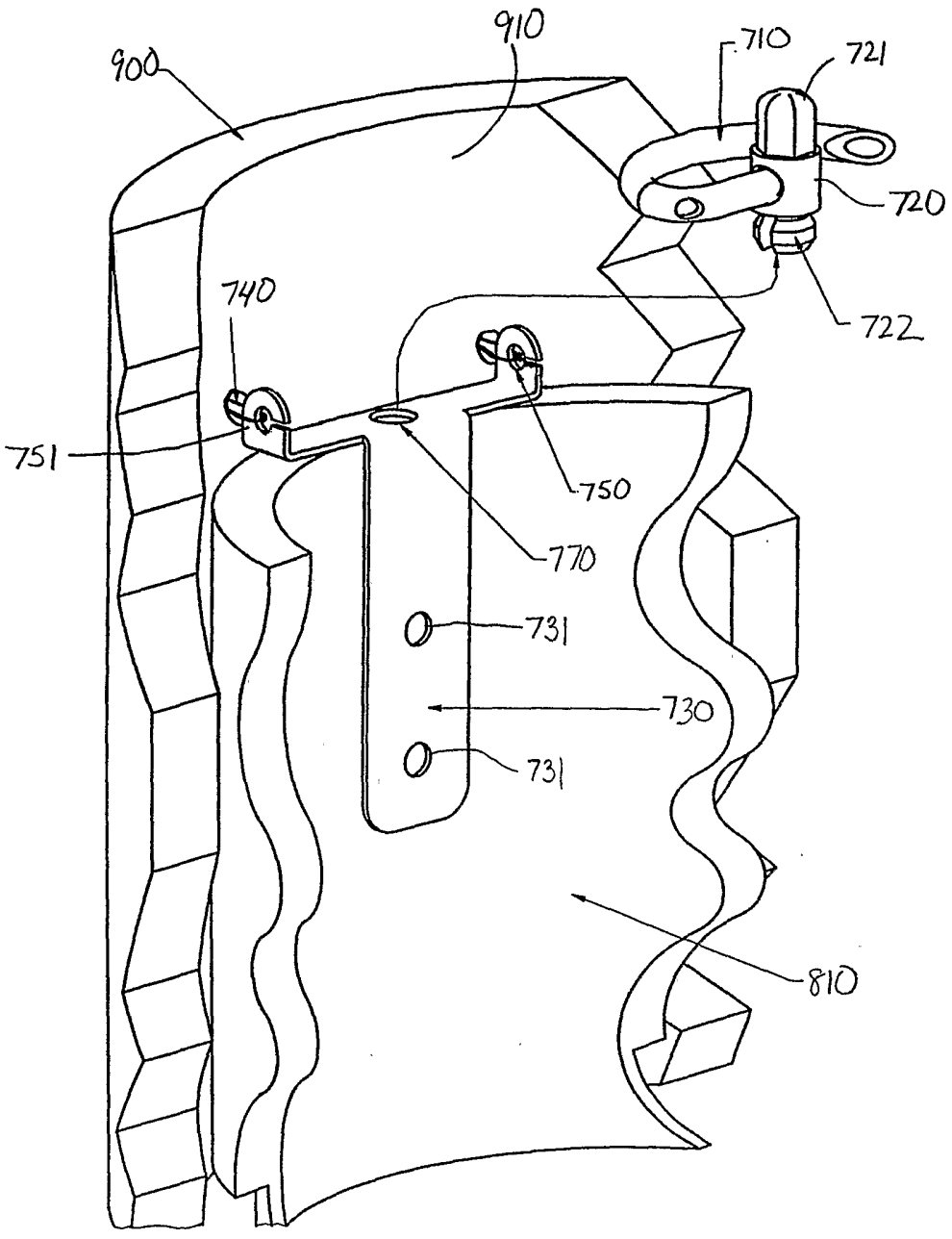

Fig. 10

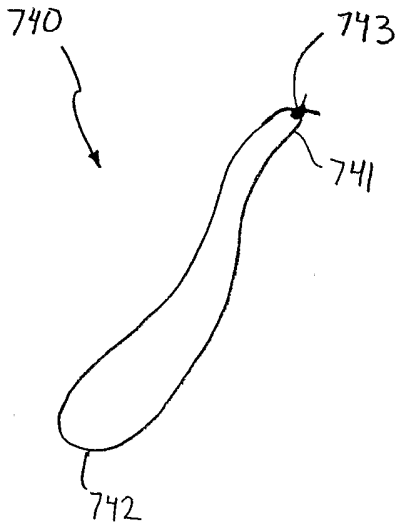

Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/01601

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/04

US CL : 623/23.64

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/11.11, 23.64, 23.65; 600/037

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,254,642 B1 (TAYLOR) 03 July 2001 (03.07.2001), see entire document.	1-19
A	US 6,004,347 A (MCNAMARA ET AL) 21 December 1999 (21.12.1999), see entire document.	1-19
A	US 5,314,473 A (GODIN) 24 May 1994(24.05.1994), see entire document.	1-19

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

23 July 2004 (23.07.2004)

Date of mailing of the international search report

03 NOV 2004

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Form PCT/ISA/210 (second sheet) (July 1998)